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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,188	02/12/2004	Peter James Jenkins	08505.0020	3089
7590	01/26/2005			
Therese Hendricks Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 1300 I Street, N.W. Washington, DC 20005-3315				EXAMINER PESELEV, ELLI
				ART UNIT 1623
				PAPER NUMBER DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/776,188	JENKINS ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Elli Peselev	1623.

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 30 November 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 30-38 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____ .                                  |

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Claims 30-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 30, 2004.

Applicant's election without traverse of claims 1-29 in the reply filed on November 30, 2004 is acknowledged.

Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-16 are directed to the treatment of diabetes and its complications and associated conditions.

The only data presented in the specification is directed to the effect of Gibberellin A3 or Gibberellin A4/A7 mixture on diabetic rats (Pages 21-23 of the specification, Examples 4-5). It is not clear from the examples in the specification whether rats has type 1 or type 2 diabetes. Therefore the effectiveness of the claimed methods on the different types of diabetes cannot be ascertained. Further, there is no evidence of record showing the effectiveness of the claimed methods for the treatment of complications and conditions associated or related to diabetes. Due to the highly unpredictable nature of treating various types of diabetes, complications and associated

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or related conditions, there is a good reason to doubt the effectiveness of the claimed methods for the treatment of said conditions.

Further, the term "glycosidic" (all occurrences) lacks enablement in that it encompasses monosaccharides, disaccharides and polysaccharides. The specification fails to provide any guidance on how to chose glycosidic moieties which will result in compounds having the desired activity. Further, there is a good reason to doubt that a compound substituted by a monosaccharide will have the same activity as a compound substituted by a polysaccharide.

The terms "allyl", "aryl", "arylalkyl", "amidine" and "unsaturated or saturated ring" (all occurrences) lack enablement in that said terms have not been limited to any number of carbon atoms and it would take an undue amount of experimentation to determine which specific moieties will result in a compound having the desired activity.

Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 8, the phrase "including" (line 2) renders the claim indefinite because it is unclear what other steps are included in the claim i.e. the scope of the invention cannot be determined.

Regarding claim 1, the phrase "including" (second to last line) renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The term "derivatives" (claim, 1,8, 11, 17 and 29) renders the claims indefinite since the scope of the claims cannot be determined. Note that the specification fails to provide definition of the term "derivatives".

Regarding claim 5, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

There is no antecedent basis in claim 1 for the terminology "related conditions" in claims 13-14.

Regarding claim 16, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oden (U.S. Patent No. 5,580,857) the International Patent WO 96/20703, the International Patent No. 94/26240 or the European Patent No. 0024951 B1.

Each of Oden, the International Patents and the European Patent discloses the claimed gibberellins containing composition and a method for preparing the same. The claimed compositions and method for preparing the same are anticipated by the cited prior art.

In addition, if there are any differences between the claimed compositions and the prior art compositions, the differences would appear to be minor in nature and the claimed compositions, which fall within the scope of the prior art compositions, would have been *prima facie* obvious from the said references' disclosures to a person having ordinary skill in the art at the time the instant invention was made.

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Claims 1-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Davis et al (Journal of the American Podiatric Medical Association 79:1, 24-26 (January 1989) or the International Patent No. WO 96/20703.

Davis et al disclose a composition containing gibberellins and administration of said composition to diabetic animals. The treatment of diabetes would have been inherent from such an administration. The claimed methods and compositions are anticipated by or are deemed *prima facie* obvious over Davis et al.

The international Patent discloses compositions containing gibberellins and a method for treating ulcers and wounds (page 3). Since the terminology "complications and associated conditions" encompasses ulcers and wounds , the claimed compositions and methods are anticipated by or are deemed *prima facie* obvious over the International Patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

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